DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FOI

JUL 29 1998

TRANSMITTED VIA FACSIMILE

Albert P. Mayo
Director, Regulatory Affairs
Organon
375 Mount Pleasant Avenue
West Orange, NJ 07052

RE: **NDA#** 20-071
Desogen(desogestrel and ethinyl estradiol) Tablets
MACMIS ID# 6854

Dear Mr. Mayo:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of several promotional materials for Desogen that are false, misleading, or otherwise in violation of the Federal Food, Drug and Cosmetic Act. These materials include but are not limited to a journal ad (ID #ORG2-106), a leaflet (ID # ORG2-142A), and brochures (ID #s ORG2-107, OR2C-186, -190, -194, -195, -198, -204, -229).

Specifically, DDMAC has the following objections:

1. The campaign "My body knows the difference," is a false and misleading presentation that implies that Desogen is different, if not superior, to other oral contraceptives based on its low androgenicity. No clinically significant differences between Desogen and other oral contraceptives have been demonstrated in adequate and well-controlled comparative studies. Furthermore, there are no adequate and well-controlled studies that have demonstrated that the body can sense a difference between oral contraceptives.

2. Claims that imply that Desogen is superior to other oral contraceptive products because it has less side effects (i.e., hirsutism or weight gain) are false or misleading because they lack adequate substantiation from well-controlled clinical trials.

3. The claim that Desogen is for perimenopausal patients is false or misleading because Desogen's efficacy in the specific perimenopausal

patient population has not been demonstrated in adequate and well-controlled clinical studies, and Desogen is not indicated for perimenopausal symptoms.

4. The claim that breakthrough bleeding is not a concern for Desogen users is lacking fair balance because it is minimizes Desogen's risk of breakthrough bleeding.

5. These materials are lacking in fair balance because the claim "serious as well as minor side effects have been reported with the use of oral contraceptives..." is not adequate risk information. For example, the information in the black box warning is not included in the promotional materials. Also, the bolded warning that oral contraceptives do not protect against sexually transmitted diseases is not included in many pieces.

6. The claim that Desogen is the "One that's convenient" is false or misleading because it is an unsubstantiated superiority claim. Desogen is as convenient as other oral contraceptives. Other oral contraceptives have "first-day or Sunday start for convenient cycle timing" and they have some form of cycle pack or blister pack that are designed to help compliance.

7. The claim "the worlds #1 prescribed OC" is misleading without adequate substantiation, and the promotional materials for Desogen, lack adequate reference for this claim.

DDMAC requests that Organon immediately discontinue these and any other promotional materials, or activities, that involve the same or similar messages. Organon should respond, in writing, with its intent to comply with DDMAC's request by August 12, 1998. This response should include a list of all violative materials that will be discontinued and a description of Organon's plan for addressing the issue.

If you have any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds you that only written communications are considered official.

In all future correspondence regarding this matter, please refer to the MACMIS ID # 6854 in addition to the NDA number.

Sincerely,

/S/

Lisa L. Stockbridge, Ph.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications